

# Notice of Allowability

Application No.

10/624,006

Examiner

Suzanne M. Mayer, Ph.D.

Applicant(s)

IOANNES ET AL.

Art Unit

1653

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to a phone call made to Mr. Daniel Nesbitt on Jan. 11, 2005.
2. ☒ The allowed claim(s) is/are 3-11, 13-16, 19 and 21.
3. ☒ The drawings filed on 21 July 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claim 1: Cancel

Claim 2: Cancel and replace it with new claim 21.

Claim 3: No change.

Claim 4: The composition according to claim 3, wherein the composition further comprises ~~an other~~ another protein, an LPS, a polysaccharide, or ~~an other~~ another hemocyanin or a subunit thereof, wherein the CCH-A subunit is at least 95% pure.

Claim 5: The composition according to claim 4, wherein the other hemocyanin comprises a dissociated CCH-B subunit.

Claim 6: A method for treating a disease state selected from bladder cancer, melanoma, mammary cancer or ovary cancer, comprising the step of administering to a patient with the disease state an effective anti-tumor amount of a composition comprising:

a. a product comprising a dissociated CCH-A subunit isolated from the hemocyanin of the marine gastropod *Concholepas concholepas*, wherein the CCH-A

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subunit has a molecular weight of about 404 kDa, is stable in the absence of  $\text{Ca}^{2+}$  and  $\text{Mg}^{2+}$  and is at least 95% pure, and

b. a physiologically acceptable isotonic buffer.

Claim 7: A method according to claim 6 wherein the composition further comprises ~~an other~~ another protein, a LPS, a polysaccharide or another hemocyanin or a subunit thereof.

Claim 8: The method of claim 7 wherein the other hemocyanin is a dissociated CCH-B subunit.

Claim 9: No change.

Claim 10: No change.

Claim 11: No change.

Claim 12: Cancel.

Claim 13: A method for enhancing the immunogenicity of a hapten or a peptide, comprising the step of administering with the hapten or the peptide an amount of a product comprising a dissociated CCH-A subunit isolated from the hemocyanin of the marine gastropod *Concholepas concholepas*, wherein the CCH-A subunit has a molecular weight of about 404 kDa, is stable in the absence of  $\text{Ca}^{2+}$  and  $\text{Mg}^{2+}$ , is at least 95% pure, and wherein the product is an immunogen.

Claim 14: No change.

Claim 15: No change.

Claim 16: No change.

Claim 17: Cancel.

Claim 18: Cancel.

Claim 19: The method according to claim 13, wherein the product further comprises a dissociated CCH-B subunit.

Claim 20: Cancel.

Claim 21: (New) A method for immunostimulating the innate or adaptive response of vertebrates comprising administering a therapeutically effective amount of a dissociated CCH-A subunit from *Concholepas conchcolepas* as an immunotherapeutic agent to treat cancers or tumors found in animals or humans.

In the Specification, p. 16, Table 2, in the Protocol section of Day 1: change Complete to Incomplete. (Thus it will read: 400 µg of antigen in Incomplete Freund's Adjuvant, subcutaneous and intradermic)

### **REASONS FOR ALLOWANCE**

2. The following is an examiner's statement of reasons for allowance: the claims as stated are novel and free of the prior art.

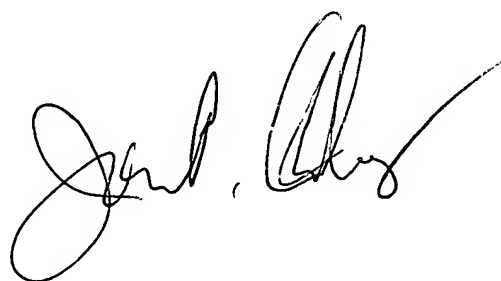
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Smm*  
11 January, 2005  
SMM

A handwritten signature in black ink, appearing to read "Jon Weber", with a large, stylized flourish extending from the end.

**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**